Pharmaceutical Consultancy Services

Quality Management MODULE 1

Exploring the role of the Qualified Person

18-19 Apr & 23-25 May 2023

This training provides insight into an integrated approach on quality management as a good business practice in the pharmaceutical and related industries to safeguard the quality of their products.

TARGET AUDIENCE

- Professionals in pharmaceutical, biotechnological and medical device industries, Professionals in institutions and Contract Research Organizations (CRO's), Hospital pharmacists and Postgraduate students.
- Accreditation is granted for hospital and public pharmacists!

LEARNING GOALS

- Apply the basic principles of quality management from a regulatory and business perspective
- Identify elements of applicable GMP regulations and GMP expectations across the product life-cycle
- Understand current regulatory developments and their business impact

RESULTS

- Insight into the integrated approach on Quality Management to safeguard product quality.
- Tools to realize and improve, pro-actively and on an ongoing basis, effective quality management across the various stages of the product lifecycle.
- Thorough understanding of the specific regulatory responsibilities of senior management, functional leaders, the Qualified Person and Responsible Person.

CONTENTS

- Quality Management as a good business practice
- Basic Principles of Quality Management
- The specific regulatory role and responsibility of Senior Management, the QP & RP
- Essential Quality Management System elements
- Trending, and management reviews
- Lean Manufacturing and Quality Management
- Current regulatory developments
- Inspection highlights
- Managing regulatory inspections
- The critical impact of culture and behavior on compliance
- QP experiences
- Industry, hospital environment, international setting
- Real-life challenges: APIs, excipients, QP declarations, and more!
- Real-life case studies

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Quality Management MODULE 1

MODULE LEADER

Dr. Désirée Vendrig – Vendrig in Pharma

After 10 years as a Senior GMP Inspector for the Dutch Inspectorate for Healthcare and Youth (then known as IGZ), Désirée fulfilled various Global Quality Management positions at Teva and was a registered QP and RP. Nowadays, Désirée is an independent GxP consultant.

GENERAL INFORMATION

Educational Form Classroom learning
Date(s) 18-19 Apr & 23-25 May 2023
Location Area of Utrecht, the Netherlands

RELATED COURSES

Quality Management in Drug Development
This three-day training provides insight into the regulatory requirements for drug development.

Quality Management in Sterile Manufacturing
Three days of training on sterility assurance challenges in the pharmaceutical industry and hospital pharmacies.

Quality Management in Manufacturing of Biopharmaceuticals
Three days on manufacturing biopharmaceuticals & quality aspects.

What makes a PCS training so special?

640

More than 640 participants so far!

35

This is the 35th edition of this training.

92%

92% of participants would recommend this training to others.

8,2

The average rating for this module is 8.2 out of 10.